

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/840,257	SCOTT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sow-Fun Hon	1772	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and terminal disclaimer filed 12/22/05.
2. ☒ The allowed claim(s) is/are 63-65.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: FR 98/02983.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>01/06/06</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input checked="" type="checkbox"/> Other <u>See Continuation Sheet.</u></li> </ol> |
|---|---|

Continuation of Attachment(s) 9. Other: The drawings dated 04/23/01 are accepted by the Examiner..

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Rosemary Miano on January 06, 2006. The application has been amended as follows:
2. In the amendment dated 2/22/05, to conform with 37 C.F.R. 1.121(c), insert above Claim 63 - - Claims 1-62 (canceled). - -, and insert below Claim 65 - - Claims 66-81 (canceled). - -
3. In the amendment to the specification, dated 4/23/01, second line, after "on December 24, 1998," insert - - abandoned, - -
4. In the amendment to the specification, dated 3/11/02, page 2, below the paragraph "Figure 2 is a graph .... gelatin capsules.", insert - - Figure 3 is a graph showing the dissolution results under USP XXIII dissolution test conditions for the capsules prepared in accordance with the present invention. - -
5. The following is an examiner's statement of reasons for allowance: The closest cited prior art of record, US 5,264,223 fails to teach, or suggest, even in combination with US 3,664,963 and US 4,627,850, the combination of a capsule comprising 90 to 97 % by weight of a polyvinyl alcohol, 2 to 7 % by weight of water, a setting system comprising 0.01 to 10 % by weight of a hydrocolloid or mixtures thereof and a sequestering agent selected from the group consisting of ethylenediaminetetraacetic

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acid, acetic acid, boric acid, citric acid, edetic acid, gluconic acid, lactic acid, phosphoric acid, tartaric acid or salts thereof, metaphosphates, dihydroxyethylglycine, lecithin, beta cyclodextrin and combinations thereof, and 0.001 to 5 % by weight of cations, based on the total weight of the capsule. None of the references teach a sequestering agent selected from the group consisting of ethylenediaminetetraacetic acid, acetic acid, boric acid, citric acid, edetic acid, gluconic acid, lactic acid, phosphoric acid, tartaric acid or salts thereof, metaphosphates, dihydroxyethylglycine, lecithin, beta cyclodextrin and combinations thereof. US 6,517,865 has been removed as valid prior art by the terminal disclaimer dated 12/22/05.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system through Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

*S. Hon*

Sow-Fun Hon

*01/06/08*

*[Signature]*  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  
*1772*

*1/9/08*